

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 USC § 371

VAS-5395

US APPLICATION NO (If known, see 37 CFR 1.5)

unknown 09/936098

INTERNATIONAL APPLICATION NO
PCT/US99/30974INTERNATIONAL FILING DATE
23 December 1999PRIORITY DATE CLAIMED
8 March 1999TITLE OF INVENTION
Directional Guidewire

APPLICANT(S) FOR DO/EO/US

Stu Foster, Geoffrey H. White, Weiyun Yu

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- 1 ☒ This is a **FIRST** submission of items concerning a filing under 35 USC § 371 ☐
- 2 ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC § 371 ☐
- 3 ☒ This is an express request to begin national examination procedures (35 USC § 371(f)) ☐ The submission must include items (5), (6), (9) and (21) indicated below ☐
- 4 ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31) ☐
- 5 ☒ A copy of the International Application as filed (35 USC § 371(c)(2))
- a ☐ is attached hereto (required only if not communicated by the International Bureau) ☐
- b ☒ has been communicated by the International Bureau ☐
- c ☐ is not required, as the application was filed in the United States Receiving Office (RO/US) ☐
- 6 ☐ An English language translation of the International Application as filed (35 USC § 371(c)(2)) ☐
- a ☐ is attached hereto ☐
- b ☐ has been previously submitted under 35 USC § 154(d)(4) ☐
- 7 ☒ Amendments to the claims of the International Application under PCT Article 19 (35 USC § 371(c)(3))
- a ☐ are attached hereto (required only if not communicated by the International Bureau) ☐
- b ☐ have been communicated by the International Bureau ☐
- c ☐ have not been made; however, the time limit for making such amendments has NOT expired ☐
- d ☒ have not been made and will not be made ☐
- 8 ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 USC § 371(c)(3)) ☐
- 9 ☐ An oath or declaration of the inventor(s) (35 USC § 371(c)(4)) ☐
- 10 ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 USC § 371(c)(5)) ☐

Items 11 to 20 below concern document(s) or information included:

- 11 ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98 ☐
- 12 ☐ An assignment document for recording ☐ A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included ☐
- 13 ☐ A **FIRST** preliminary amendment ☐
- 14 ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment ☐
- 15 ☐ A substitute specification ☐
- 16 ☐ A change of power of attorney and/or address letter ☐
- 17 ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter and 35 USC § 821 - 1.825 ☐
- 18 ☐ A second copy of the published international application under 35 USC § 154(d)(4) ☐
- 19 ☐ A second copy of the English language translation of the international application under 35 USC § 154(d)(4) ☐
- 20 ☒ Other items or information:
- Certificate of Mailing
Return Postcard

09/936098

21 ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO ☐ \$1000.00

International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO ☐ \$860.00

International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ☐ \$710.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) ☐ \$690.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) ☐ \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

CALCULATIONS PTO USE ONLY

\$ 860

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30
months from the earliest claimed priority date (37 CFR 1.492(e)) ☐

\$ 130

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	6 - 20 =		x \$18.00	\$ 0
Independent claims	2 - 3 =		x \$80.00	\$ 0
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$ 0

TOTAL OF ABOVE CALCULATIONS = \$ 990

☐ Applicant claims small entity status ☐ See 37 CFR 1.27 ☐ The fees indicated above
are reduced by 1/2 ☐ +

\$

SUBTOTAL = \$ 990

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)) ☐

\$

TOTAL NATIONAL FEE = \$ 990

Fee for recording the enclosed assignment (37 CFR 1.21(h)) ☐ The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) ☐ \$40.00 per property +

\$

TOTAL FEES ENCLOSED = \$ 990Amount to be
refunded:

\$

charged:

\$

a ☐ A check in the amount of \$ _____ to cover the above fees is enclosed ☐

b ☒ Please charge my Deposit Account No. 501225 in the amount of \$ 990 to cover the above fees ☐
A duplicate copy of this sheet is enclosed ☒

c ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. _____ ☐ A duplicate copy of this sheet is enclosed ☐

d ☒ Fees are to be charged to a credit card ☐ **WARNING:** Information on this form may become public ☐ **Credit card**
information should not be included on this form ☐ Provide credit card information and authorization on PTO-2038 ☐

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
1.137 (a) or (b)) must be filed and granted to restore the application to pending status ☐

SEND ALL CORRESPONDENCE TO:

Peter J. Gluck
Edwards Lifesciences Corp.
Legal Dept.
One Edwards Way
Irvine, CA 92614

SIGNATURE

Peter J. Gluck

NAME

REGISTRATION NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

VAS-5395

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

unknown 09/936098

INTERNATIONAL APPLICATION NO.

PCT/US99/30974

INTERNATIONAL FILING DATE

23 December 1999

PRIORITY DATE CLAIMED

8 March 1999

TITLE OF INVENTION

Directional Guidewire

APPLICANT(S) FOR DO/EO/US

Stu Foster, Geoffrey H. White, Weiyun Yu

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- 1 ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371 ☐
- 2 ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371 ☐
- 3 ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) ☐ The submission must include items (5), (6), (9) and (21) indicated below ☐
- 4 ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31) ☐
- 5 ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
- a ☐ is attached hereto (required only if not communicated by the International Bureau) ☐
- b ☒ has been communicated by the International Bureau ☐
- c ☐ is not required, as the application was filed in the United States Receiving Office (RO/US) ☐
- 6 ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) ☐
- a ☐ is attached hereto ☐
- b ☐ has been previously submitted under 35 U.S.C. 54(d)(4) ☐
- 7 ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
- a ☐ are attached hereto (required only if not communicated by the International Bureau) ☐
- b ☐ have been communicated by the International Bureau ☐
- c ☐ have not been made; however, the time limit for making such amendments has NOT expired ☐
- d ☒ have not been made and will not be made ☐
- 8 ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)) ☐
- 9 ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)) ☐
- 10 ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)) ☐

Items 11 to 20 below concern document(s) or information included:

- 11 ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98 ☐
- 12 ☐ An assignment document for recording ☐ A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included ☐
- 13 ☐ A **FIRST** preliminary amendment ☐
- 14 ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment ☐
- 15 ☐ A substitute specification ☐
- 16 ☐ A change of power of attorney and/or address letter ☐
- 17 ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter 2 and 35 U.S.C. 821 - 1.825 ☐
- 18 ☐ A second copy of the published international application under 35 U.S.C. 54(d)(4) ☐
- 19 ☐ A second copy of the English language translation of the international application under 35 U.S.C. 54(d)(4) ☐
- 20 ☒ Other items or information:
- Certificate of Mailing
Return Postcard

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PCT Application of:

APPLICANTS: Stu Foster, Geoffrey H. White, Weiyun Yu

SERIAL NUMBER: PCT/US99/30974

FILED: 23 December 1999

TITLE: Directional Guidewire

Box PCT
Attn: DO/EO/US
Commissioner of Patents and Trademarks
Washington, D. C. 20231

Documents Sent: Certificate of mailing
Transmittal Letter of US Designated/Elected Office
(DO/EO/US) Concerning a Filing Under 35 U.S.C. 371
Duplicate sheet

CERTIFICATE OF MAILING UNDER CFR 1.10

I hereby certify that the above-identified documents are being deposited with the United States Postal service as "Express Mail" No. EL599139505US, in an envelope addressed to: Box PCT, Attn: DO/EO/US, Commissioner of Patents and Trademarks, Washington, D.C. 20231 on September 7, 2001.

By:

Jan Lamonica
Jan Lamonica

DIRECTIONAL GUIDEWIRE

Background of the Invention

Field of the Invention

The present invention relates to a guidewire for use in medical applications and, in particular, to improvements in guidewires used in the placement of intraluminal grafts.

Description of the Related Art

The placement of prosthetic devices, such as stents and grafts, intraluminally and the conduct of operative procedures intraluminally has grown dramatically in recent years. In many of these placements and procedures, it is necessary to initially position a guidewire into a desired part of the lumen of a desired vessel or duct, such as a blood vessel. Once an initial guidewire is in place, a catheter or other tubular device may be positioned over the guidewire and used to convey another guidewire, prosthesis, an endoscope or a surgical instrument into the desired blood vessel or duct.

There are a variety of techniques used to position guidewires intraluminally, however, there are often problems encountered by medical practitioners in achieving the desired placement of a guidewire. One technique that is employed is the use of directional catheters that direct a guidewire passing therethrough in a desired direction. Such a directional catheter may, for example, having a curved end that directs a guidewire passing therethrough and exiting therefrom in a desired direction such as into a branching vessel.

Summary of the Invention

According to a first aspect, the present invention consists in a directable medical guidewire for insertion through a bodily vessel or cavity, the guidewire comprising an elongate resiliently flexible body having a main portion which

will normally assume a straight configuration, and an end portion contiguous with one end of the main portion which will normally assume a curved configuration, the guidewire being characterized in that the curved configuration of the end portion has a first section that normally has a first curvature and a second section that normally has a second different curvature to that of the first section.

For purposes of this specification, the normal configuration of the guidewire according to the present invention is taken to be the configuration adopted by the guidewire on suspension of the guidewire, outside the body, from its end distal the end portion and allowed to hang freely. It is, therefore, expected that the normally straight main portion of the guidewire would extend substantially vertically when the guidewire was suspended from its distal end. Similarly, the normal curvature of any portion of the guidewire is the curvature adopted by the guidewire when suspended as described above. In use, the configuration assumed by portions of the guidewire will vary from their normal configuration due to the resiliently flexible nature of the guidewire as it is passed through the bodily vessel or cavity. The configuration of the guidewire during storage or distribution may also vary from that normally assumed. For example, a guidewire might be coiled and then packaged for distribution and only when removed from the packaging could it assume its normal configuration.

In one embodiment of the present invention, the second portion can be contiguous with an end of the first portion. In a further embodiment, the end portion of the guidewire can have a third section contiguous with an end of the second section that normally has a third different curvature to that of the second section. Instead of having a curvature, the third section can also be normally substantially straight relative to the curvature of the second section. It can also

be envisaged that the end portion could have a fourth or further number of curved or straight sections, depending on how tortuous vessels being treated are.

The first, second and further sections of the end portion can each normally have the curvature of a notional circle, ellipse or the like curved shapes. For example, the first section can have the curvature of a first notional circle having a first radius, and the second portion the curvature of a second notional circle having a second different radius to that of the first circle. In another example, the first portion can have the curvature of a notional circle and the second portion the curvature of a notional ellipse. In a still further example, the first portion can have the curvature of a notional ellipse and the second portion the curvature of a notional circle. In yet a further example, the first section can have the curvature of a first notional ellipse and the second section the curvature of a second notional ellipse.

The first and second section of the end portion of the guidewire can be separated by an intermediate section. The intermediate section can normally assume a straight configuration or can normally assume a curved configuration with a normal curvature different to that normally assumed by the first and second sections. If the intermediate portion normally assumes a curved configuration, the intermediate portion can have the curvature of a notional circle, ellipse or parabola.

In a further embodiment, the end portion has an angle of inflection between the first and second sections such that the first and second curved sections are of opposite curvature. The curvature of the first and second sections can also define notional planes, with the curvature of the second section being in a different notional plane to that of the first section.

In the embodiment of the invention having a normally straight intermediate portion, the normal curvature of the first section is preferably such that the intermediate portion makes an angle of between 10 and 135° to the

longitudinal axis of the normally straight portion. When the guidewire is used in the placement of intraluminal grafts in the aorta and associated iliac arteries, the angle is more preferably between 20 and 45°, and most preferably about 30°. The curvature of the second curved section is also preferably such that the

5 longitudinal axis of the intermediate portion makes an angle between 10 and 135° with a notional straight line extending from the end of the second section or an actual normally straight portion contiguous with the free end of the second section. When the guidewire is used for placement of intraluminal grafts in the aorta and associated iliac arteries, this angle is more preferably between 30 to

10 60°, most preferably about 45°.

The length of the intermediate portion can be set to suit the application of the guidewire. For use in the placement of intraluminal grafts, the length can be between 1 and 6 cm, more preferably about 3 and 4 cm.

The guidewire can be fabricated from a metal or metal alloy. For

15 example, the guidewire can be fabricated from nitinol alloy. The guidewire can be coated along its length with a suitable material to reduce friction, such as a biocompatible silicone based lubricant.

In a second aspect, the present invention comprises a kit having a guiding catheter that has disposed therein a directable medical guidewire as

20 defined herein.

In a still further aspect, the present invention comprises a method for positioning a guidewire as defined herein within a bodily vessel that is branching off a first vessel, comprising the steps of introducing a kit according to the second aspect of the present invention into the first vessel.

Briefly stated, there is provided that novel and enhanced guidewire

25 iterations are provided with curvilinear end portions and methods of use of the same for endovascular grafting; for example, are taught.

According to a feature of the present invention there is provided a directable medical guidewire having two ends and an outer surface for insertion through a lumen comprising: an elongate resiliently flexible body having a main portion biased into a first configuration; and, an end portion contiguous with one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to that of the first section.

According to another feature of the present invention there is provided a method of emplacing the guidewire defined by claim 1, wherein said guidewire is adapted to be suspended outside of a body having a lumen, and whereby the end distal said end portion hangs freely.

In yet another feature of the present invention there is provided a method of using the guidewire defined by claim 1, including the steps of varying the configuration of said guidewire during storage by coiling said guidewire into a spring biased state, packing said guidewire; removing said guidewire; and reconfiguring an unbiased orientation in of said guidewire in said lumen.

In yet another feature of the present application there is provided a guidewire defined by claim 1, further comprising at least one of a metal and alloy selected from the group consisting of nitinol, nickel, titanium, stainless steel, elgiloy, palladium and the like super-elastic or flexible substantially metallic or magnetic combinations.

In yet still another feature of the present invention there is provided a guidewire defined by claim 1, wherein said outer surface is coated by at least one biocompatible substance selected from the group consisting of PET, PTFE, silicone based lubricants and the like plastic-based materials.

A kit which comprises a guiding catheter having a directable medical guidewire disposed therein; a first means for emplacing the guidewire; a means

for adjusting the emplaced guidewire; and a second means for emplacing the guidewire.

Brief Description of the Drawings

5 Hereinafter by way of example only, preferred embodiments of the present invention are now described with reference to the accompanying drawings, in which:

FIG. 1 is a simplified diagrammatic representation of a ventral view of a patient having an aortic aneurysm bridged by a trouser graft;

10 FIGS. 2a-i show the stages of carrying out a method of intraluminally placing a trouser graft into a patient, which uses the invention, defined herein:

FIG. 3a-d are side elevational views of different embodiments of a guidewire according to the present invention;

15 FIG. 4 is a vertical sectional view of one embodiment of a possible bifurcated graft mounted over a delivery catheter for use in the method depicted in Figs. 2a-I; and

FIG. 5 is a vertical sectional view of one embodiment of a tubular graft mounted over a delivery catheter for use in the method depicted in Figs. 2a-i.

Detailed Description Of the Invention

20 The present invention can be used in any surgical procedure where it is necessary to direct a guidewire into a bodily vessel whether it be for the placement of an intraluminal graft of another surgical procedure. Examples of vessels in which it can be necessary to direct a guidewire include the renal, vesical and iliac arteries.

25 The present invention is hereinafter described with reference to the example of the placement of an intraluminal graft into a patient to achieve at least one of the bridging and occlusion of an aortic aneurysm. Those having a

modicum of skill likewise are cognizant of related procedures and locations, including, but not limited to thoracic sites and the like.

As seen in Figure 1, the aorta 10 branches into the right and left iliac arteries 12, 13. The aortic aneurysm 14 is located between the renal arteries 15, 16 and extends down the left iliac artery 13. One means of bridging the aneurysm 14 is to use a trouser graft 17, which is provided with a bifurcation to form a pair of short tubular extensions 19, 19a that are connected to tubular grafts 17a, 17b that extend down the iliac arteries 12, 13 respectively. One such trouser graft is described in Australian Patent Specification No AU-A-78035/94, the description of which is incorporated herein by reference.

The method for positioning an intraluminal graft will now be described with reference to Figures 2a-i. In carrying out the method an incision or puncture is made to expose the one of the femoral arteries (eg: ipsilateral), which flows from the corresponding iliac artery, and using the Seldinger needle technique, a 0.035" diameter floppy tipped flexible guidewire is inserted into and through the femoral artery and then the iliac artery 12 into the aorta 10 such that it traverses the aneurysm 14. An 8 French haemostatic sheath is then introduced over the wire to control bleeding. An angiographic catheter is then introduced to allow an angiogram to be taken of the patient to show the position of the renal arteries 15, 16 and other relevant anatomical structures in the patient.

An Amplatz extra stiff AES guidewire 23 (0.035" diameter) is then passed through the angiographic catheter into the aorta 10. After withdrawal of the angiographic catheter, the stiff guidewire 23 is left in situ. A sheath 21, preferable of 24 French, and a dilator are then introduced into the aorta 10 over the stiff guidewire 23 (see Figure 2a). A balloon catheter 24 is then introduced into the sheath 21.

As seen in Figure 4, the balloon catheter 24 is a delivery catheter which is pre-packaged with a bifurcated graft 17, having a bifurcation point 17c, and

ipsilateral extension 19, a contralateral extension 19a, and a thin catheter 25 containing a guidewire 26 extending in a first direction up through the ipsilateral tubular graft extension 19 and then in a second different direction into the contralateral extension 19a.

5 When the balloon catheter 24 is positioned within the aorta 10 correctly, the sheath 21 is partially withdrawn to free the graft so that the balloon 20 may be inflated (see Figure 2b). The inflation of the balloon 20 of catheter 24 expands the upstream end of the first graft 17 and causes it to engage its upstream end against the aorta wall above the aneurysm but downstream of the renal arteries 15,16.

10 The first graft 17 is of such a length that the short tubular extensions 19, 19a are disposed wholly within the aorta 10. The balloon 20 is then deflated but the balloon catheter is left in place for the time being (see Figure 2c). Deflation of the balloon 20 allows blood to flow down the graft 17 distending the first graft 17 and the tubular extensions 19, 19a.

15 The thin catheter 25 is preferably 3 French and resiliently flexible guidewire 26 is preferably comprised of a nitinol alloy core with a hydrophilic coating. Once the first graft 17 is in place, it is necessary to extend the guidewire 26, which is depicted in its normal configuration in Fig. 3a outside the body, has a straight main portion 50 and an end portion 51 having a curved configuration.

20 The end portion 51 is comprised of a first curved section 52 and a second curved section 53 separated by a relatively short linear intermediate portion 54. The curvature of the first curved portion 53 is preferably such that the intermediate portion 54 makes an angle of about 30° to the longitudinal axis 55 of the straight main portion 50. For other applications of the guidewire or, where required for
25 the present illustrative application, the curvature of the first curved section can, however, be varied such that the angle lies in the range 10 to 135°. The curvature of the second curved section 53 is such that the longitudinal axis 56 of the normally straight intermediate portion is at an angle of about 45° to a notional

straight line 57 (depicted in phantom) extending from the end of the second curved section 53. As with the first curved section, the curvature of the second curved section can be varied such that the angle lies somewhere in the range of 10 to 135°. The length of the intermediate portion 54 in the depicted embodiment is 3 cm. The double curvature of the guidewire 26 allows the guidewire 26 to be guided through the contralateral iliac artery and appropriately enter the contralateral femoral artery 13a (see Fig.2c).

Once the guidewire 26 is correctly placed in the contralateral femoral artery 13a, which is cross-clamped, and an arteriotomy affected. If the guidewire 26 has been guided fully into the contralateral femoral artery 13a, the guidewire 26 is simply recovered by drawing the guidewire through the incision or puncture made in the artery 13a. If the guidewire 26 has not been guided fully along the femoral artery 13a, a snare or similar device can be introduced through the contralateral femoral artery 13a to grab the guidewire 26 and draw it back to the puncture or incision site for retrieval. Once the guidewire 26 is retrieved, the thin catheter 25 is then withdrawn via the ipsilateral side and another catheter 27 is then fed through the contralateral femoral artery 13a over the guidewire 26 until it is within the first graft 17 and reaches at least the top of the contralateral tubular extension 19a. The guidewire 26 is then withdrawn and a stiffer guidewire 30 is inserted through the contralateral femoral artery 13a into the catheter 27. The catheter 27 is then removed and a catheter sheath 21a, and a dilator are introduced over the stiff guidewire 30 (see Figure 2e).

Prior to extending the guidewire 26 into the contralateral iliac and femoral arteries, a catheter sheath (similar to catheter sheath 21) can be extended upstream through the contralateral femoral and iliac arteries to reduce any tortuosity that may be present in these arteries and so facilitate guiding of the guidewire 26 therethrough.

A second balloon catheter 24a, such as is depicted in Fig.5, on which is packaged a second tubular graft 17b is then introduced through catheter sheath 21a until its upper end is well within the contralateral tubular extension 19a at its upper end and with the iliac artery 13 at its lower end. The balloon 20a on the catheter 24a is inflated such that the upper end of graft 17b is frictionally engaged with the contralateral tubular extension 19a (see Figure 2f). The inflation of the balloon 20a on the catheter 24a supports the graft 17 during the withdrawal of the first balloon catheter 24 through the ipsilateral iliac artery 12. The balloon 20 is then deflated and the catheter 24a is maintained in place to provide continued support for the grafts 17, 17b in the aorta 10 while the third graft is positioned.

The catheter sheath 21a is then removed (see Figures 2f and 2g) and a third balloon catheter, on which is packaged a tubular graft 17a, (the third balloon catheter can be identical to that depicted in Fig.5) is introduced into the sheath 21 on guidewire 23. It is advanced until its upstream end is within the ipsilateral extension 19 and, following partial withdrawal of the sheath 21, is then deployed. The third graft 17a positioned on the third balloon catheter is thus urged at its upstream end into contact with the ipsilateral extension 19 and its downstream end into contact with the right iliac artery 12 (see Figure 2h).

The stiff guidewires 23 and 30 are now withdrawn and the contralateral incision or puncture sutured. A second angiographic examination now takes place and if the grafts 17, 17a and 17b are correctly placed and functioning, the haemostatic sheath 21 is withdrawn and the right femoral incision sutured. The result is a functioning trouser graft bridging an aneurysm as is depicted in Fig. 2i.

The operation may be carried out using a general anesthetic, an epidural anaesthetic, an epidural anesthetic, or in suitable cases, using only a local anesthetic.

Alternative guidewires to that depicted as 26 in Fig. 3a are depicted in Figs. 3b-c. Figure 3b depicts a resiliently flexible guidewire body 60 having a

normally straight main portion 50 and an end portion 51. The end portion 51 is comprised of a first curved section 61 having the curvature of a first circle, a second curved section 62 having the curvature of a different circle, and a curved intermediate portion 63 having the curvature of an ellipse. Fig. 3c depicts a
5 resiliently flexible guidewire 70 having a normally straight main portion 50 and a curved end portion 51, with the curved end portion 51 comprised of a first curved section 71 having the curvature of a notional circle and a second curved section 72 contiguous with the end of the first curved section 71 and having the curvature of a different notional circle. Guidewires having end portions with still further
10 curved configurations can also be envisaged.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in
15 all respects as illustrative and not restrictive.

09036098-0220002

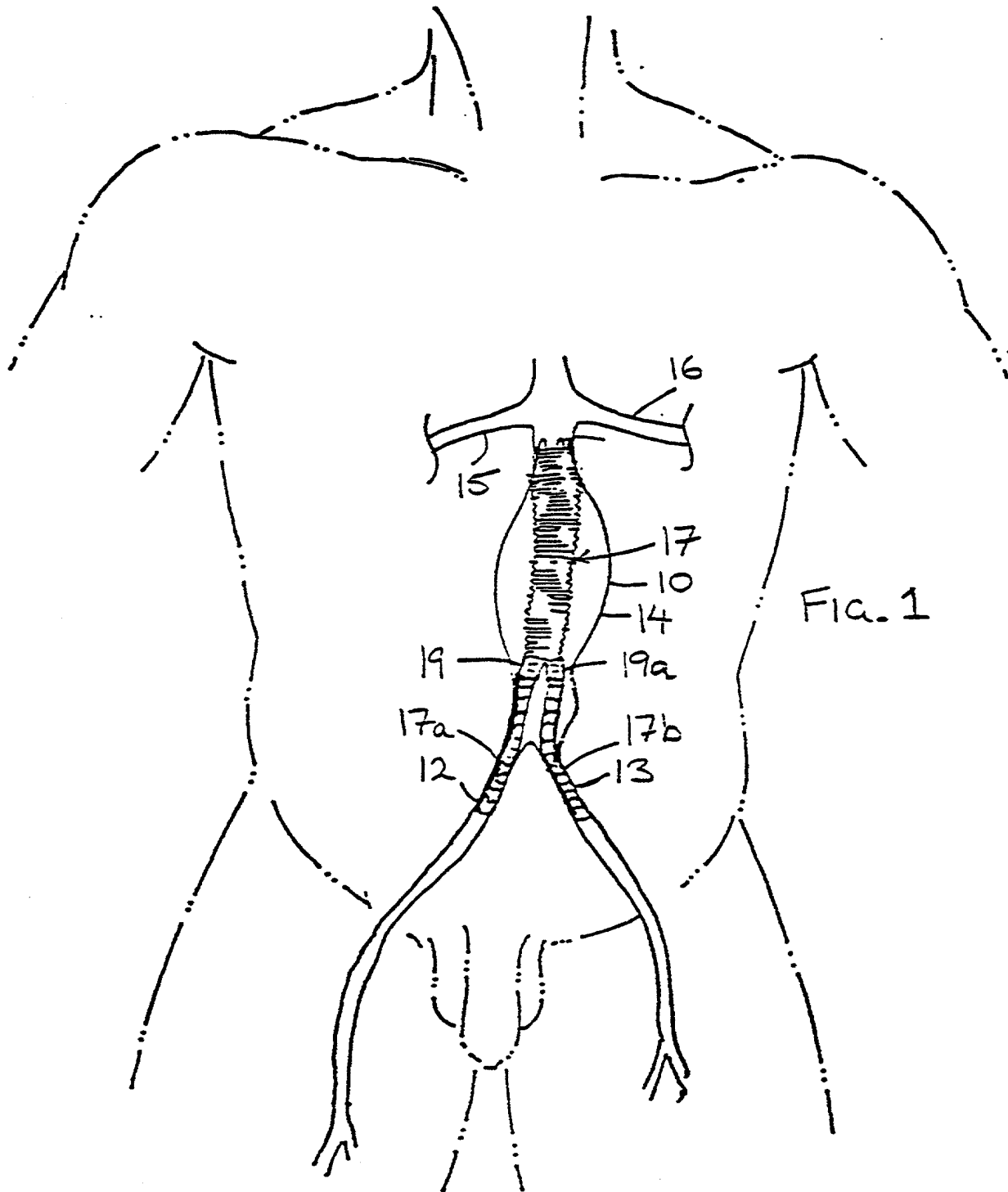
WHAT IS CLAIMED IS:

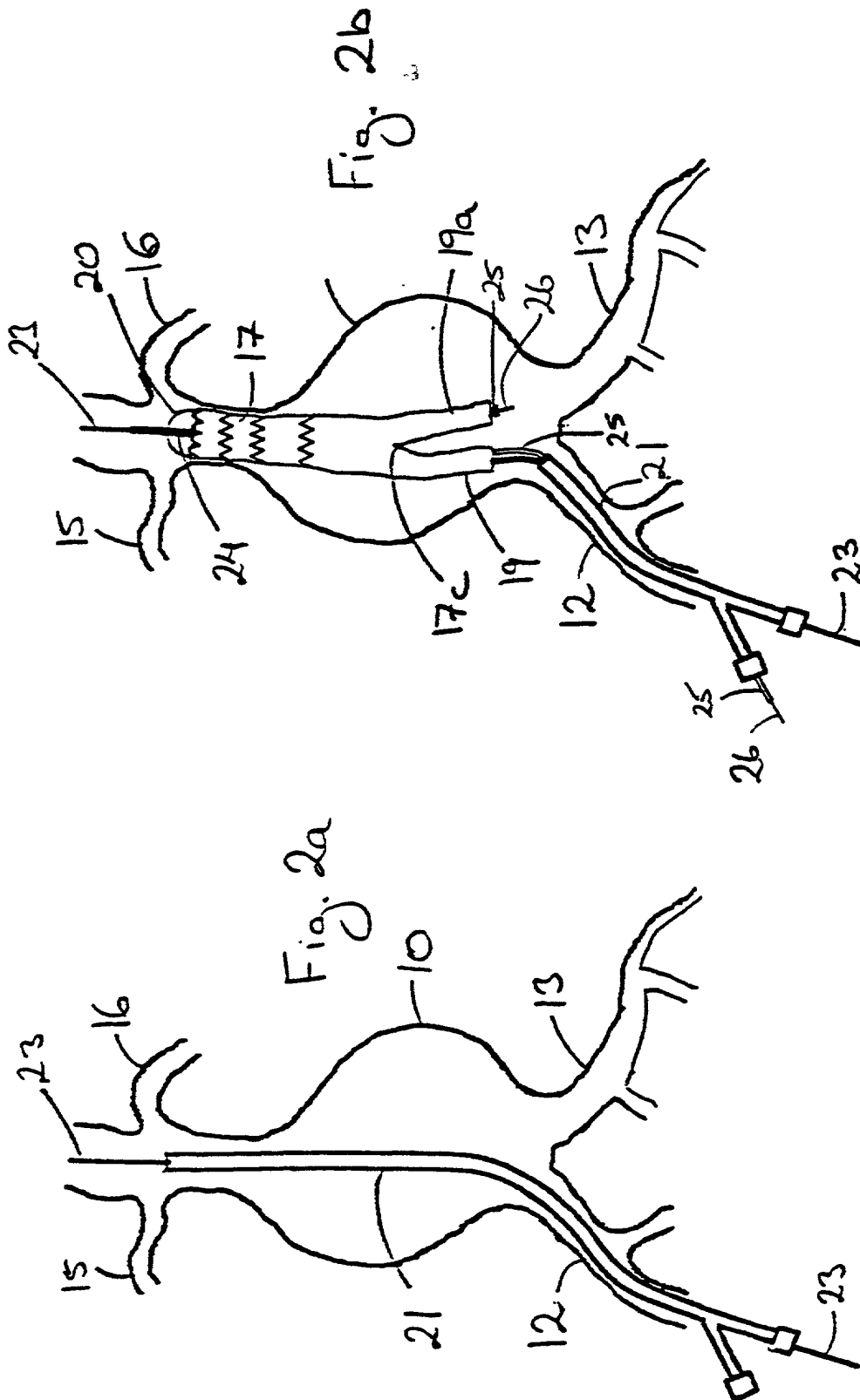
1. A Directable Medical Guidewire having two ends and an outer surface for insertion through a lumen comprising:
5 an elongate resiliently flexible body having a main portion biased into a first configuration; and, an end portion contiguous with one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to that of the first section.
10
2. A method of emplacing the guidewire defined by claim 1, wherein said guidewire is adapted to be suspended outside of a body having a lumen, and whereby the end distal said end portion hangs freely.
15
3. Method of using the guidewire defined by claim 1, including the steps of varying the configuration of said guidewire during storage by coiling said guidewire into a spring biased state, packing said guidewire; removing said guidewire; and reconfiguring an unbiased orientation in
20 of said guidewire in said lumen.
4. Guidewire defined by claim 1, further comprising at least one of a metal and alloy selected from the group consisting of nitinol, nickel, titanium, stainless steel, elgiloy, palladium and the like super-elastic or
25 flexible substantially metallic or magnetic combinations.
5. Guidewire defined by claim 1, wherein said outer surface is coated by at least one biocompatible substance selected from the group

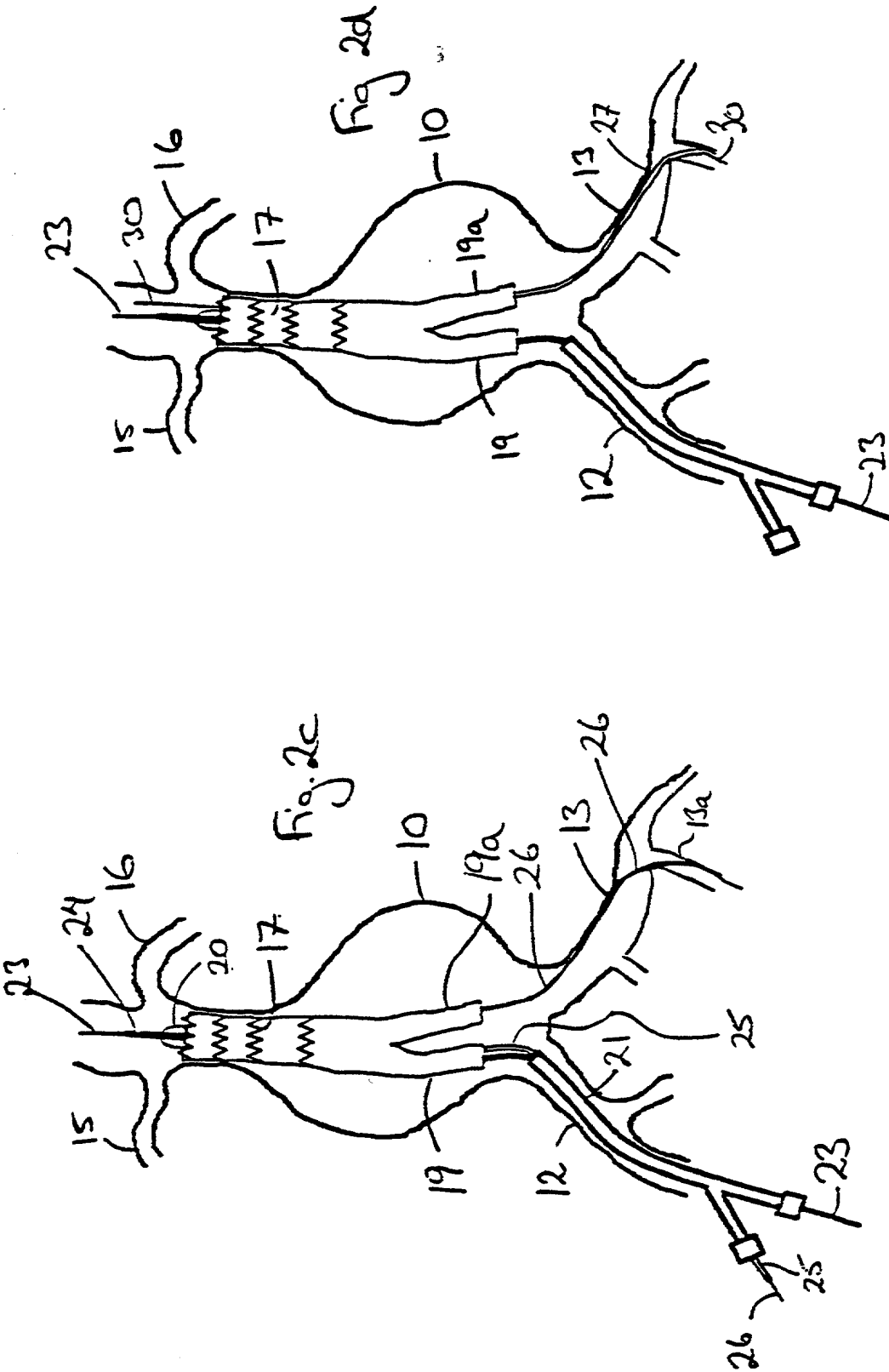
consisting of PET, PTFE, silicone based lubricants and the like plastic-based materials.

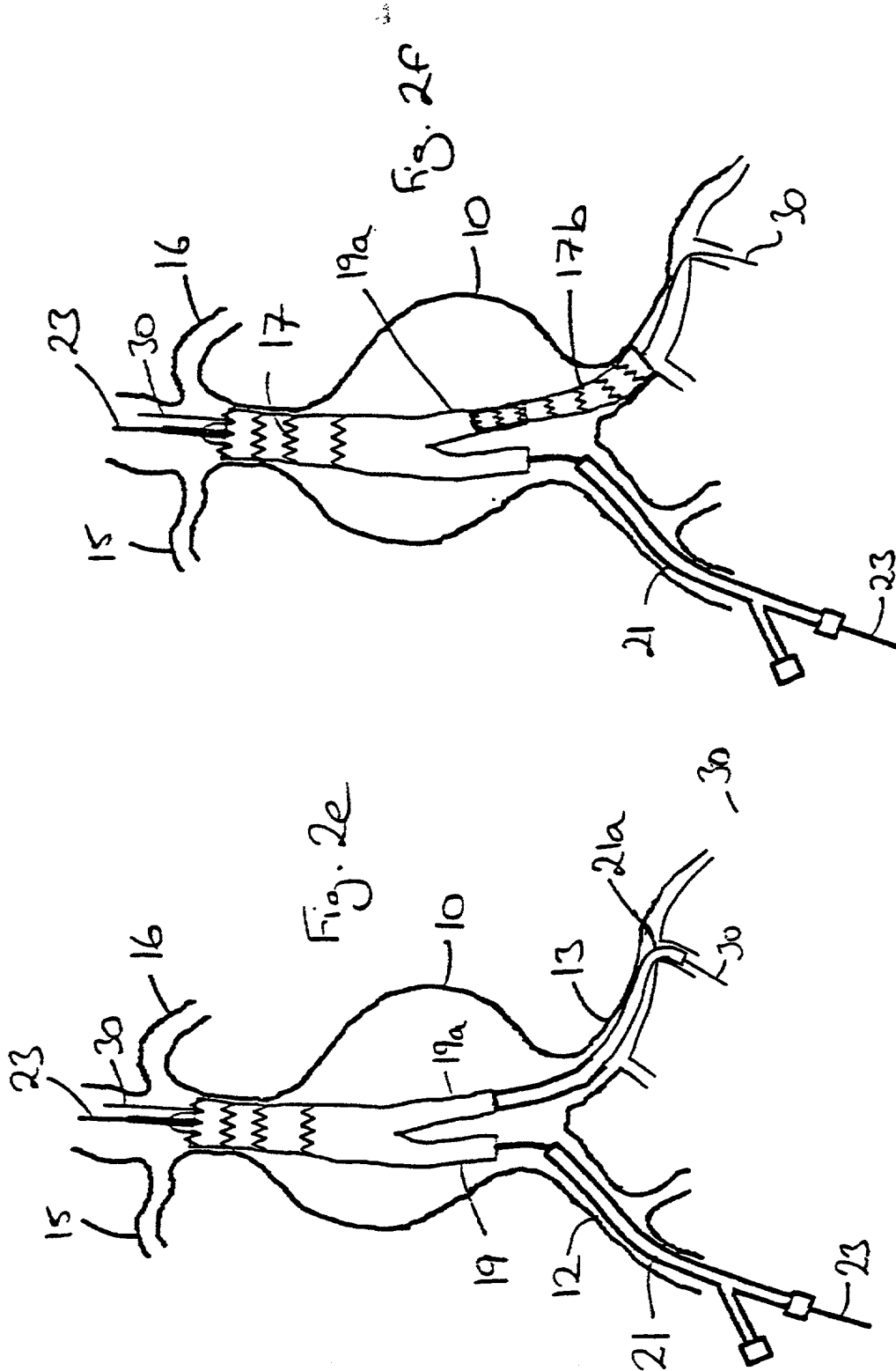
- 5 6. A kit which comprises a guiding catheter having a directable medical guidewire disposed therein; a first means for emplacing the guidewire; a means for adjusting the emplaced guidewire; and a second means for emplacing the guidewire.

200220" 36092660









200220" 8609E660

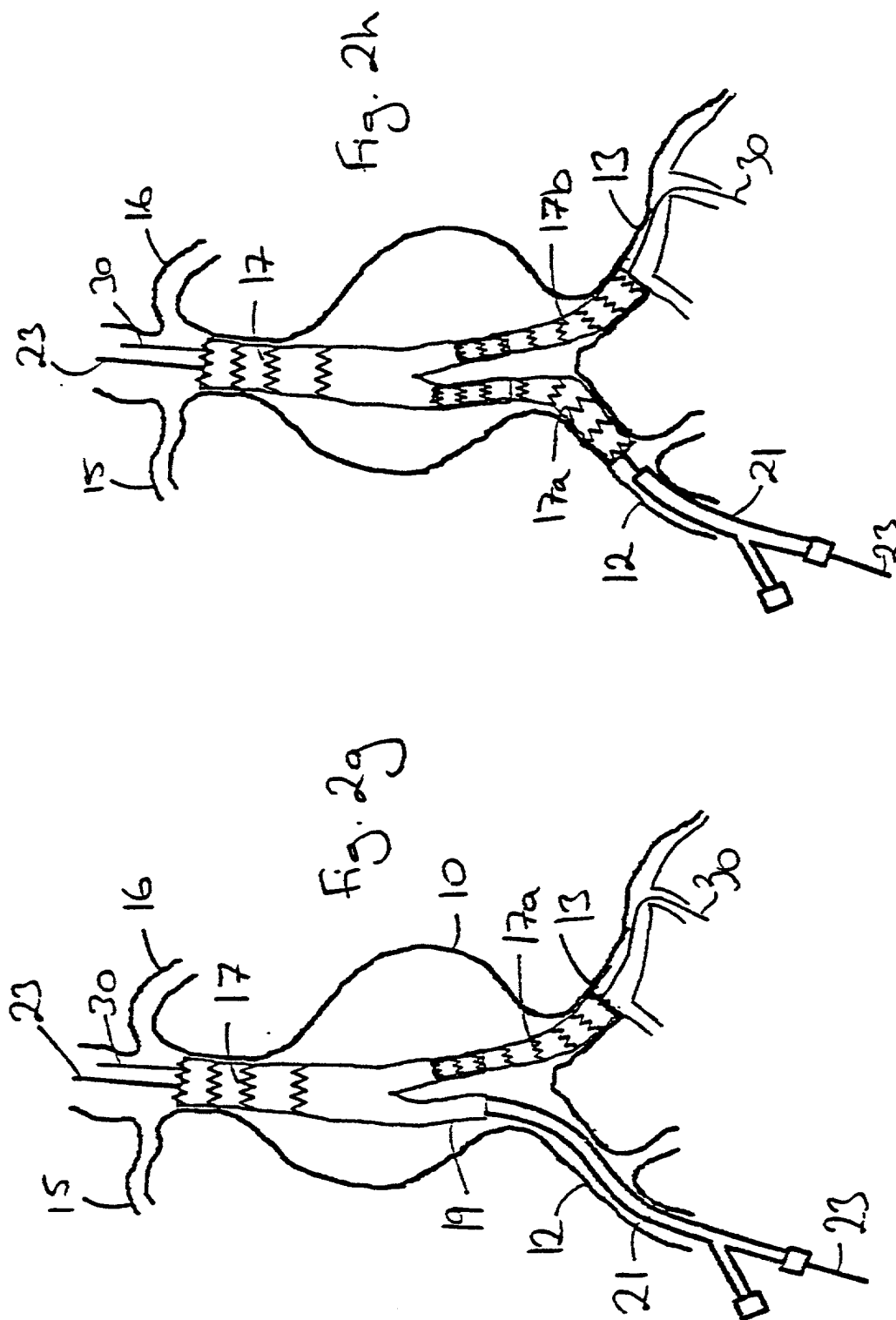
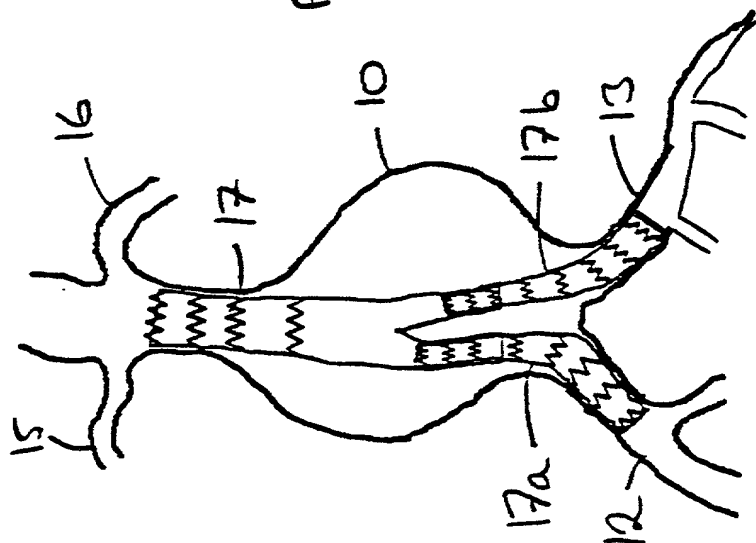
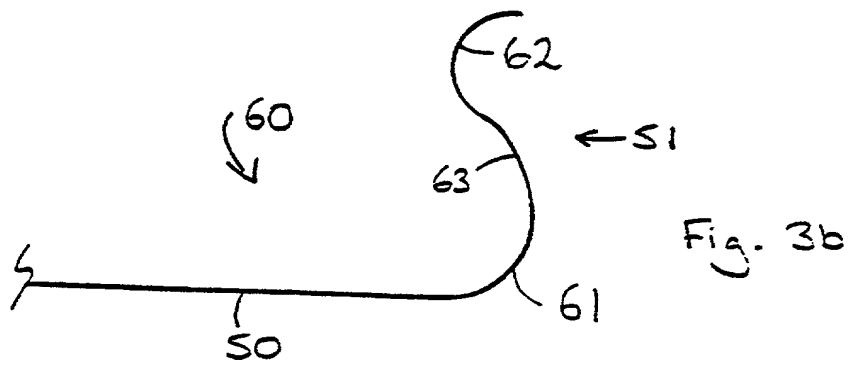
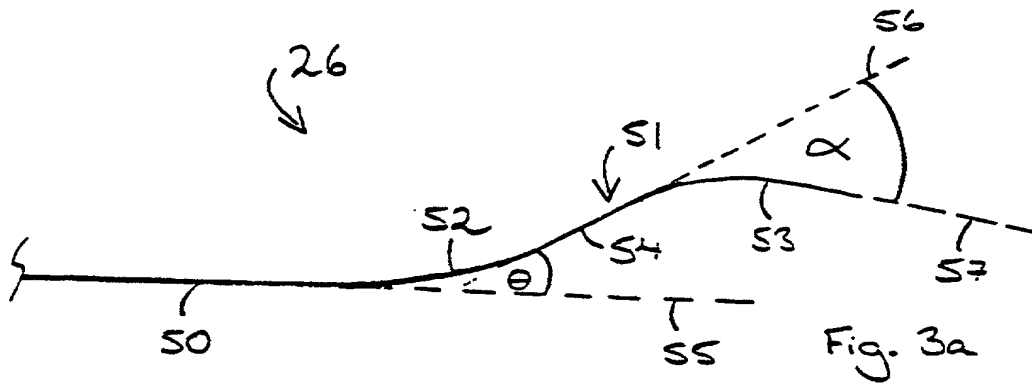


Fig. 2i



200220-8609E660



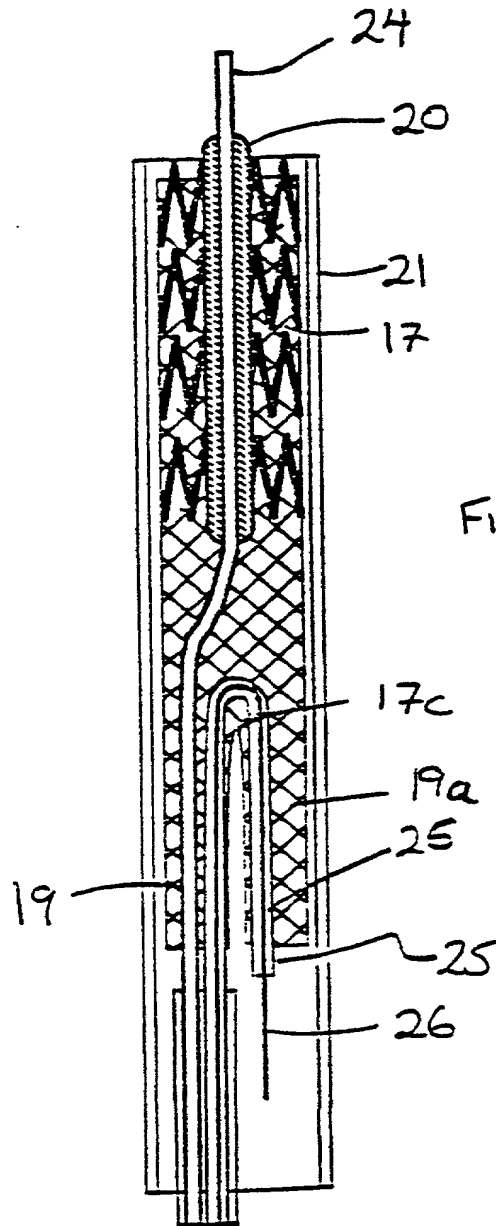
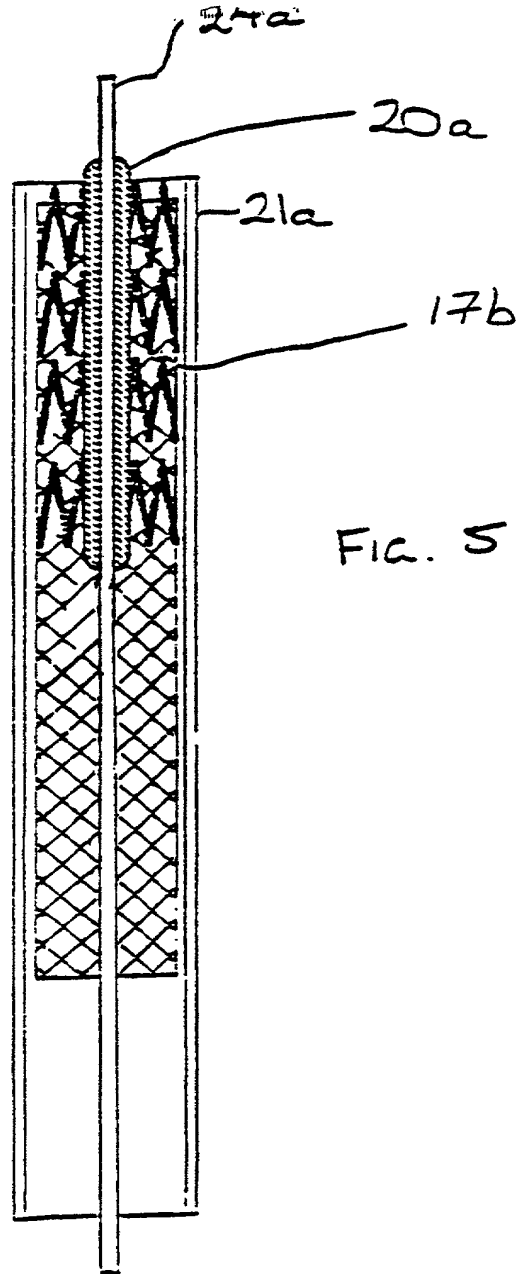


FIG. 4

0936098:022002

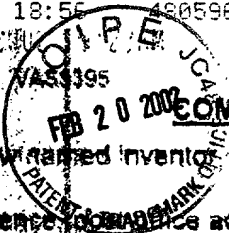
9/9



09/936098 02/00

Patent No. VAS9395

Page 1 of 2

**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My Residence, Mailing address and citizenship are as stated below next to my name.

I believe I am an original, first and sole inventor (if only one name is listed below) or an original joint inventor (if several names are listed below) of the subject matter which is claimed and for which a patent is sought in the invention entitled Directional Guidewire, the specification of which

(a) ☐ is attached hereto

or

(b) ☒ was filed on September 7, 2001 as United States Application No. 09/935, 098.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to the examination of this application as defined in Title 37, Code of Federal Regulations, §1.56(a).

CIP Application Duty: If the present application is a continuation-in-part of any prior application(s), including any listed below, or in the above-identified application, I acknowledge the duty to disclose information that is material to the examination of this application as defined in Title 37, Code of Federal Regulations, §1.56(a) which would be material between the filing date of the prior application(s) and the national or PCT international application(s) of this application.

I hereby state which priority benefits under Title 35, United States Code, §119 of any foreign or provisional application(s) for patent or inventor's certificate listed below and have also identified below any foreign application(s) for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign or Provisional Application(s)Priority Claimed

<u>Number</u>	<u>Country</u>	<u>Filing Date</u>	<u>Yes</u>	<u>No</u>
31,007	AU	03/08/99	X	

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
PCT/US95/30974	12/23/99	Pending

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office and in all the competent International Authorities connected therewith: Debra D. Condino, Reg. No. 31,007; Peter J. Gluck, Reg. No. 38,022; Lena Vinitskaya, Reg. No. 39,448 and John Christopher James, Reg. No. 40,680.

Address all correspondence and telephone calls to: Peter J. Gluck, Reg. No. 38,022

Edwards Lifesciences LLC

Law Dept.

One Edwards Way, Irvine, CA 92614

Telephone: (949) 250-6801, Facsimile: (949) 250-6850

FEB 13 2002 9:23AM

EDWARDS INV DEPT 949 550 0000

NO. 1515 P. 35

Docket No. VAS 5595

Page 2 of 2

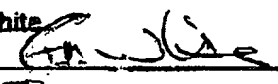
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or

first joint inventor: Stuart L. Foster 2-00Inventor's signature: X Date: 12 Feb 2002Residence: 22181 WestcliffMission Viejo, California 92691 CACitizenship: US

Post Office Address: same

Full name of second

joint inventor: Geoffrey H. WhiteInventor's signature: X Date: 12 Feb 2002Residence: 22 Nicholson StreetEast Balmain, NSW 2041 AUKCitizenship: Australia

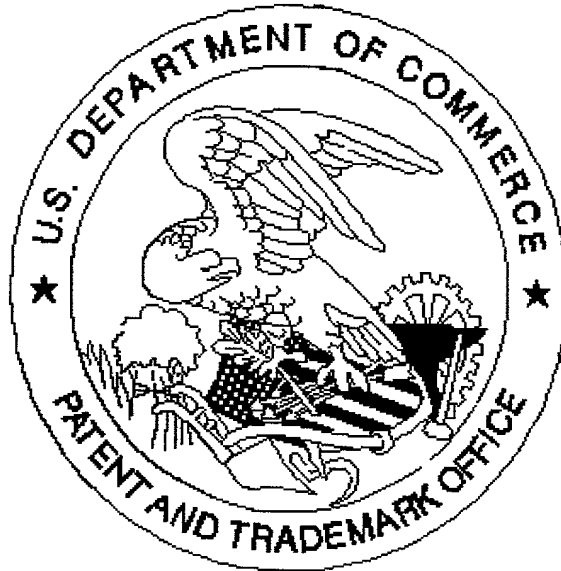
Post Office Address: same

Full name of third

joint inventor: Wei Yun Yu 2-00Inventor's signature: X Date: 11 FEB 2002Residence: Apt. 59 #8Birchgrove, NSW 2041 AUKCitizenship: Australia

Post Office Address: same

United States Patent & Trademark Office
Office of Initial Patent Examination -- Scanning Division



Application deficiencies found during scanning:

☐ Page(s) _____ of _____ were not present
for scanning. (Document title)

☐ Page(s) _____ of _____ were not present
for scanning. (Document title)

☒ Scanned copy is best available. Declarations are dark.
and line.